PATENT
32860-001073/US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPELLANTS:	Klaus ABRAHAM-FUCHS et al.	CONF. NO.:	8514
SERIAL NO.:	10/589,560	GROUP:	3626
FILED:	August 16, 2006	EXAMINER:	Fuelling, M.
FOR:	METHOD AND INFORMATION SYSTEM FOR PERFORMING A CLINICAL STUDY ON A PATIENT		

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APPELLANTS' BRIEF ON APPEAL UNDER 37 C.F.R. §41.37

Sir:

This is an Appeal Brief in response to the Final Office Action mailed November 10, 2010 and the Notice of Panel Decision from Pre-Appeal Brief Review mailed February 25, 2011. A Notice of Appeal from this Final Rejection was timely filed on February 10, 2011. Appellant submits herewith their Brief on Appeal as required by 37 C.F.R. § 41.37 along with the appropriate governmental fees as required by 37 C.F.R. § 41.20(b)(2).

41.37(c)(1)(i). REAL PARTY IN INTEREST

The real party in interest is Siemens Aktiengesellschaft.

41.37(c)(1)(ii). RELATED APPEALS AND INTERFERENCES

There are no pending Appeals related to this application.

41.37(c)(1)(iii). STATUS OF CLAIMS

Claims 1-23 are pending in this application, with claims 1, 7 and 17 being in independent form. Each of claims 1-23 stand finally rejected and are being appealed.

No claims have been cancelled

41.37(c)(1)(iv). STATUS OF AMENDMENTS

An Amendment under 37 C.F.R. § 1.116 filed February 9, 2011, in response to the November 10, 2010, final Office Action has been entered.

41.37(c)(1)(v). SUMMARY OF CLAIMED SUBJECT MATTER

The following explains the subject matter set forth in each claim argued on appeal by way of example embodiments in the specification by page and line number, and in the drawings, if any, by reference characters only to satisfy 37 C.F.R. §41.37(c)(1)(v). This concise explanation relies on example embodiments from the specification to describe the claims; however, the claims recite subject matter not limited to these example embodiments. Independent claims 1 and 6 are argued on appeal and discussed below.

A. Concise explanation of the subject matter set forth in each independent claim

1. A general discussion of the subject matter, described in the specification to assist the Board in understanding example embodiments described in the present application.

Clinical studies are commissioned and performed by various backers or sponsors such as pharmaceutical companies, clinics or state institutions. For example, new medicaments, methods for surgical intervention, therapies or diagnostic devices are tested on patients. The purpose of the clinical study is often approval of the tested product before an approval authority (e.g., the Food and Drug Administration).[1]

A special study doctor who frequently sees the patient throughout the course of the study, usually in a clinic, is responsible for performing the study on a patient. Rules are established to which the study doctor must adhere. The rules are typically known as a study protocol. The study doctor examines the patient, for example regularly at prescribed intervals. Preferably, the patient consults with the study doctor for all health issues, including health issues which are not related to the study. For example, the study doctor performs control examinations, tests or interviews on the patient, in order to document the properties or mode of action of the medicament etc. studied in the study, or else

[1] See page 1, lines 5-21 of the substitute specification filed August 16, 2006.

to monitor the patient's general health condition. The determined results are incorporated into the study as study data.[2]

Studies relating to new medicaments, newly developed active agents, or active agent combinations are typically administered to the patient. The administration is performed during various development phases of the medicament. The study doctor is fully informed about the study, for example, the study doctor knows the precise chemical composition of the new active agents or the properties of a particular therapy and its interactions with known medicaments or diagnostic and treatment methods. The study doctor can thus adapt their entire treatment of the patient as regards examination methods, therapies, medication etc. to the study and all interactions with the patient.[3]

The study doctor being fully informed is important in certain situations. For example, consider an incidental disease of the patient which is not related to the study. The incidental disease requires an interaction of the study doctor with the patient and is not covered by the study protocol. The study doctor must take the study doctors' knowledge about the study into account in the study doctors' diagnosis and treatment of the incidental disease. For example, interactions between new and existing medicaments may endanger the patient by mutually incompatible active agents. The study doctor can also select their examination or treatment methods as much as is possible so that the examination or treatment

[2] See page 1, lines 30-36 and page 2, lines 1-8 of the substitute specification filed August 16, 2006.
[3] See page 2, lines 10-21 of the substitute specification filed August 16, 2006.

methods do not affect the study or make the patient unsuitable for further participation in the study.[4]

An interaction of the patient with a doctor who is not involved with the clinical study, and is not therefore informed about the clinical study, is problematic. Such a doctor is, for example, the patient's usual family doctor or an emergency doctor who treats the patient in an accident situation. The interaction is problematic because the patient may exhibit modified reactions to treatments which are generally standard. In addition, test results may be out of the ordinary as a result of the clinical study. For example, the patient may exhibit a modified blood count or modified blood pressure or pulse values, which are harmless in the scope of the clinical study but which an uninformed doctor would regard as cause for concern. A doctor not informed about the clinical study could thus be led to a misdiagnosis or mistreatment of the patient.[5]

Problems exist not only for the patient, whose health might suffer, but also for the backer or sponsor of the study since an examination or treatment of the patient which is incompatible with the study could mean that the patient has to be excluded from the study. The success or quality of the clinical study in turn depends on the patients associated with the study not being excluded. Further, typically significant financial investment or losses for the backer or sponsor often depend thereon.[6]

For at least the above reasons, conventional art provides a patient in a clinical study with a multiplicity of documents which contain as detailed as

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[4] See page 2, lines 23-34 of the substitute specification filed August 16, 2006.
[5] See page 3, lines 1-15 of the substitute specification filed August 16, 2006.
[6] See page 3, lines 17-24 of the substitute specification filed August 16, 2006.

possible a description of the clinical study. The patient has been obliged to inform a non-study doctor, who is interacting with them, about the study and let the non-study doctor see the documents. Therefore, patients participating in a clinical study have needed to take all the relevant documents about the current study with them and present them to the treating doctor.[7]

The non-study doctor has had to study and evaluate the documents provided to them, and possibly communicate with those responsible for the study in order to obtain certain further information about the relevant patient or the study. For example, the precise composition of a new active agent is generally intended to be kept secret and is not therefore known in the documents with which the patient is provided, but must be released to the treating doctor in a health-risk situation for the patient.[8]

In example embodiments a method for carrying out a clinical study involving a patient includes storing study-related data associated with a protocol of the clinical study, storing patient-related data associated with the patient and the clinical study and reading by a computer associated with a non-study doctor assigned to the patient at least one of the study-related data and the patient-related data. Each of the study-related data and the patient-related data are stored on a memory. The memory is a computer readable storage medium. The memory is one of (1) a portable memory device transported by the patient and (2)

[7] See page 3, lines 26-34 of the substitute specification filed August 16, 2006.
[8] See page 4, lines 1-9 of the substitute specification filed August 16, 2006.

part of a data network with limited access, the limited access being authorized by the patient.[9]

The above discussion has been made for descriptive purposes and has only been made to comply with current United States Patent and Trademark Office Rules and Regulations. The above discussion should not, however, limit the claims in any way.

2. An explanation of the subject matter set forth in each independent claim, and each dependent claim argued separately, referring to the specification and/or the drawings by reference characters in accordance with 37 CFR 41.37(c)(1)(v).

Independent Claim 1

Claim 1 recites a "method for carrying out a clinical study involving a patient." This feature reads on, for example, a clinical study 2 that is, for example, intended to examine a new blood pressure reducing formulation.[10]

Claim 1 further recites the method includes "storing on a memory, study-related data associated with a protocol of the clinical study." This feature reads on, for example, memory 12 which has study data 14 relating to the study 2 stored on memory 12.[11]

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[9] See page 5, lines 1-12 and page 5, line 31 to page 6, line 2 of the substitute specification filed August 16, 2006.
[10] See FIG. 1 and page 12, lines 5-6 of the substitute specification filed August 16, 2006.
[11] See FIG. 1 and page 12, lines 31-35 of the substitute specification filed August 16, 2006.

Claim 1 further recites the method includes "storing, on the memory, patient-related data associated with the patient and the clinical study." This feature reads on, for example, study doctor 8 connects the memory 12 to the study doctors personal computer 15 as a data input device, and adds to the memory 12 a part of the patient data 16 relating to the patient 4 and relevant to the study 2.[12]

Claim 1 further recites the method includes "reading by a computer associated with a non-study doctor assigned to the patient at least one of the study-related data and the patient-related data." This feature reads on, for example, the patient 4 therefore grants family (e.g., non-study) doctor 22 access to the memory 12 by giving the family doctor 22 the memory 12. The family doctor 22 connects the memory 12 to the family doctors' 22 laptop 25. The family doctor 22 reads the study data 14 and patient data 16 out from the memory 12.[13]

Claim 1 further recites "the memory is a computer readable storage medium." This feature reads on, for example, a multiplicity of different data media may be envisaged as memories, for example diskettes, magnetic tapes, (rewritable) CD-ROMs or memory chips.[14]

Claim 1 further recites the memory is "a portable memory device transported by the patient." This feature reads on, for example, a memory 12 in the form of, for example, a USB wristwatch for the patient 4.[15]

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[12] See FIG. 1 and page 13, lines 1-6 of the substitute specification filed August 16, 2006.
[13] See FIG. 2 and page 16, lines 26-33 of the substitute specification filed August 16, 2006.
[14] See page 5, lines 1-12 and page 5, line 31 to page 6, line 2 of the substitute specification filed August 16, 2006.
[15] See FIG. 1 and page 12, lines 29-32 of the substitute specification filed August 16, 2006.

Claim 1 further recites the memory is alternatively "part of a data network with limited access, the limited access being authorized by the patient." This feature reads on, for example, alternatively the memory is part of a data network to which the data input and reading device can be connected. Authorization, which the patient may carry with them, is then required for access to the data.[16]

Dependent Claim 6

Claim 6 recites "at least one of the study-related data and the patient-related data are assigned to various classes, and the non-study doctor reads only information of one class out from the memory." This feature reads on, for example, the data to be stored in the memory may be assigned to various classes and information which is of interest only to special doctors.[17]

Independent Claim 7

Claim 7 recites an "information system for a clinical study on a patient." This feature reads on, for example, the information system for a clinical study on a patient.[18]

Claim 7 further recites the information system includes "a memory to store at least one of study-related and patient-related data." This feature reads on, for

[16] See FIG. 1 and page 11, lines 4-11 of the substitute specification filed August 16, 2006.
[17] See page 9, lines 13-24 and page 19, lines 15-30 of the substitute specification filed August 16, 2006.
[18] See FIG. 1 and page 10, lines 8-9 of the substitute specification filed August 16, 2006.

example, memory 12 which has study data 14 relating to the study 2 stored on memory 12.[19]

Claim 7 further recites the "the memory being a computer-readable medium assigned to the patient." This feature reads on, for example, a multiplicity of different data media may be envisaged as memories, for example diskettes, magnetic tapes, (rewritable) CD-ROMs or memory chips.[20]

Claim 7 further recites the memory being "a portable memory device transported by the patient." This feature reads on, for example, a memory 12 in the form of, for example, a USB wristwatch for the patient 4.[21]

Claim 7 further recites the memory alternatively being "part of a data network with limited access, the limited access being authorized by the patient." This feature reads on, for example, alternatively the memory is part of a data network to which the data input and reading device can be connected. Authorization, which the patient may carry with them, is then required for access to the data.[22]

Claim 7 further recites the information system includes "a data input device to input data being stored in the memory." This feature reads on, for example, the study doctors' personal computer 15.[23]

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[19] See FIG. 1 and page 12, lines 31-35 of the substitute specification filed August 16, 2006.
[20] See page 5, lines 1-12 and page 5, line 31 to page 6, line 2 of the substitute specification filed August 16, 2006.
[21] See FIG. 1 and page 12, lines 29-32 of the substitute specification filed August 16, 2006.
[22] See FIG. 1 and page 11, lines 4-11 of the substitute specification filed August 16, 2006.
[23] See FIG. 1 and page 13, lines 2-4 of the substitute specification filed August 16, 2006.

Claim 7 further recites the information system includes "a data reading device to read the data out from the memory." This feature reads on, for example, the study doctors' personal computer 15.[24]

Claim 7 further recites "the data reading device being accessible by a non-study doctor assigned to the patient." This feature reads on, for example, the family doctor 22 connects the memory 12 to their laptop 25.[25]

Dependent Claim 14

Claim 14 recites "wherein at least one of the study-related data and the patient-related data are assigned to various classes, and the non-study doctor reads only information of one class out from the memory." This feature reads on, for example, the data to be stored in the memory may be assigned to various classes and information which is of interest only to special doctors.[26]

Independent Claim 17

Claim 17 recites an "information system for a clinical study on a patient." This feature reads on, for example, the information system for a clinical study on a patient.[27]

Claim 17 further recites the information system includes "memory means for storing at least one of study-related and patient-related data." This feature

[24] See FIG. 1 and page 13, lines 2-4 of the substitute specification filed August 16, 2006.
[25] See FIG. 2 and page 16, line 29 of the substitute specification filed August 16, 2006.

[26] See page 9, lines 13-24 and page 19, lines 15-30 of the substitute specification filed August 16, 2006.
[27] See FIG. 1 and page 10, lines 8-9 of the substitute specification filed August 16, 2006.

reads on, for example, memory 12 which has study data 14 relating to the study 2 stored on memory 12.[28]

Claim 17 further recites the "memory means being assigned to the patient." This feature reads on, for example, a memory 12 in the form of, for example, a USB wristwatch for the patient 4.[29]

Claim 17 further recites the "the memory being a computer-readable medium assigned to the patient." This feature reads on, for example, a memory 12 in the form of, for example, a USB wristwatch for the patient 4.[30]

Claim 17 further recites the memory means being "a portable memory device transported by the patient." This feature reads on, for example, a memory 12 in the form of, for example, a USB wristwatch for the patient 4.[31]

Claim 17 further recites the memory means alternatively being "part of a data network with limited access, the limited access being authorized by the patient." This feature reads on, for example, alternatively the memory is part of a data network to which the data input and reading device can be connected. Authorization, which the patient may carry with them, is then required for access to the data.[32]

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[28] See FIG. 1 and page 12, lines 31-35 of the substitute specification filed August 16, 2006.
[29] See FIG. 1 and page 12, lines 29-32 of the substitute specification filed August 16, 2006.
[30] See FIG. 1 and page 12, lines 29-32 of the substitute specification filed August 16, 2006.
[31] See FIG. 1 and page 12, lines 29-32 of the substitute specification filed August 16, 2006.
[32] See FIG. 1 and page 11, lines 4-11 of the substitute specification filed August 16, 2006.

Claim 17 further recites information system includes "input means for storing data in the memory means." This feature reads on, for example, the study doctors' personal computer 15.[33]

Claim 17 further recites "reading means for reading the data from the memory means, the reading means being accessible by a non-study doctor assigned to the patient." This feature reads on, for example, the family doctor 22 connects the memory 12 to their laptop 25.[34]

41.37(c)(1)(vi). GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellant seeks the Board's review of the rejection of claims 1-23 under 35 U.S.C. §103(a) over U.S. Patent No. 5,072,383 to Brimm et al. ("Brimm") in view of US Patent No. 6,168,563 to Brown ("Brown").

41.37(c)(1)(vii). ARGUMENTS

A. Rejection of claims 1-23 under 35 U.S.C. §103(a) over Brimm in view of Brown

Principals of Law

The Examiner bears the initial burden of presenting a prima facie case of obviousness in rejecting claims under 35 U.S.C. § 103. *See In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993).

[33] See FIG. 1 and page 13, lines 2-4 of the substitute specification filed August 16, 2006.
[34] See FIG. 2 and page 16, line 29 of the substitute specification filed August 16, 2006.

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. *See In re Fine*, 837 F.2d 1071, 1073, 5 USPQ2d 1956, 1958 (Fed. Cir. 1988). In so doing, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), *viz.*, (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the art. "[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Furthermore, "'there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness'...[H]owever, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the would employ." *KSR Int'l Co. v. Telefax Inc.*, 127 S.Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)). Obviousness is then determined on the basis of the evidence as a whole and the relative persuasiveness of the arguments. *See Oetiker*, 977 F. 2d at 1445, 24 USPQ2d at 1444.

During examination, the claims must be interpreted as broadly as their terms reasonably allow. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004). The plain meaning of a claim term is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention" (see *Phillips v. AWH Corp.*, 415

F.3d 1303, 1313 (Fed. Cir. 2005)). Phillips also indicated that evidence for the ordinary and customary meaning of a term may be derived from "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art"

Analysis

The above rejection should be withdrawn because Brimm in view of Brown fails to render claim 1 obvious.

A.1. Rejection of claim 1

Brimm fails to teach or fairly suggest a "method for carrying out a clinical study involving a patient," as required by claim 1.

The Examiner alleges that "[w]hile Brimm does not appear to expressly use the term 'clinical study', Brimm discloses a medical regimen, as detailed above, and a clinical study is a medical regimen. Further, applicant's use of the term 'clinical study' merely is a nonfunctional description of the data."[35]

As summarized above, during examination, the claims must be interpreted as broadly as their terms reasonably allow. Further, the Examiner must give claim terms the meaning one of ordinary skill in the art at the time of the invention would give the term. The term clinical study is not a non-functional

[35] See the Office Action dated November 10, 2010, page 5, lines 7-14.

description of data, apparatuses or any other process associated with the claimed invention. Further, Brimm does not describe or disclose a clinical study.

For example, as described above, a clinical study is often used for approval of the tested product before an approval authority (e.g., the Food and Drug Administration).[36] Rules are established to which a study doctor must adhere. The rules are typically known as a study protocol. The study doctor examines the patient, for example regularly at prescribed intervals. For example, the study doctor performs control examinations, tests or interviews on the patient, in order to document the properties or mode of action of the medicament etc. studied in the study, or else to monitor the patient's general health condition. The determined results are incorporated into the study as study data.[37] Further, the plain meaning of a clinical study is "[a] research study used to find better ways to treat individuals with a specific disease, patients are evaluated after being administered a new drug or treatment."[38]

A clinical study is not merely the medical regimen of Brimm as asserted by the Examiner. By contrast, a medical regimen, as described by Brimm, relates to normal patient care as administered by a hospital. For example, Brimm generally discloses a medical information system. The medical information system is used to replace a manual, paper based, record keeping system (e.g., medical charts). Brimm discloses the medical information system replaces a "Flowsheet" chart that is usually kept at the patient's bedside. On the "Flowsheet" chart there typically

[36] See page 1, lines 5-21 of the substitute specification filed August 16, 2006.
[37] See page 1, lines 30-36 and page 2, lines 1-8 of the substitute specification filed August 16, 2006.
[38] See the definition of Clinical trial as defined in McGraw-Hill Dictionary of Scientific and Technical terms, Sixth Edition, pg. 407.

appear individual areas for Medications Records, Vital Signs, Intake/Output, Laboratory Results, and other categories which are dependent upon the patient's affliction, such as Ventilator, which would be used if a patient were placed on a ventilator.[39] Clearly Brimm discloses a medical regimen is normal patient care as administered by a hospital. Therefore, Brimm does not disclose a clinical study.

Further, the term clinical study is a term of art. As a result, the Examiner is required to ascertain the accepted meaning of a term in the art. *In re Barr*, 444 F.2d 588, 170 USPQ 330 (CCPA 1971). The Examiner has not ascertained the accepted meaning of clinical study. By contrast, the Examiner makes a conclusory statement that Applicant's use of the term "clinical study" is merely is nonfunctional. Therefore, the Examiner has not met his burden for establishing the accepted meaning for each term in claim 1.

For at least the reasons discussed above, Brimm does not teach or fairly suggest "[a] method for carrying out a **clinical study** involving a patient," as required by claim 1. Further, the Examiner has not met his burden for establishing that Brimm discloses the aforementioned limitation.

Brown fails to teach or fairly suggest a "method for carrying out a clinical study involving a patient," as required by claim 1.

Brown does not disclose the aforementioned limitation and the Examiner does not rely on Brown to disclose the aforementioned limitation. Accordingly, even assuming *arguendo* that Brown could be combined with Brimm (which

[39] See Brimm column 1, lines 41-47 and column 2, lines 1-7.

Applicants do not admit), the combination of references fails to render claim 1 obvious.

Brimm fails to teach or fairly suggest "storing on a memory, study-related data associated with a protocol of the clinical study," as required by claim 1.

The Examiner relies upon column 4, lines 10-20 of Brimm to disclose the aforementioned limitation. The Examiner alleges that "automated clinical records management" and storing data associated with a protocol of a medical regimen," discloses the aforementioned limitation.[40] Applicants respectfully disagree.

Column 4, lines 10-20 of Brimm states:

> Accordingly, it is an object of the present invention to provide an automated clinical records management system whose format closely resembles that of a manual clinical records management system, which automatically generates a time-oriented task list of tasks which must be performed for a patient in response to the entry of orders into appropriate system forms, and in which an item may be charted directly onto an appropriate system form with automatic updating of the task list and other associated form(s) upon signing by the system user.

As discussed above, and as supported by the aforementioned paragraph of Brimm, the medical information system is used to replace a manual, paper based, record keeping system (e.g., medical charts). Brimm does not disclose storing study related data and protocols. By contrast, Brimm discloses replacing/storing known hospital records associated with routine patient care. See the discussion of flowsheet charts above.

[40] See the Office Action dated November 10, 2010, page 5, lines 1-2.

Further, as described above, Brimm does not disclose anything to do with a clinical study. Consequently, Brimm has no reason to store "**study-related data associated with a protocol of the clinical study**," as required by claim 1. By contrast, Brimm stores physician orders, e.g. medication orders, lab orders, radiology orders, consultant orders (e.g. relating to care to be provided by other physicians) and orders relating to nutrition, psychiatric care, general health, etc. Brimm discloses storing physician orders associated with normal patient care.[41] Brimm is silent with regard to clinical studies and protocols associated therewith.

For at least the reasons discussed above, Brimm does not teach or fairly suggest storing on a memory, study-related data associated with a protocol of the clinical study," as required by claim 1.

Brown fails to teach or fairly suggest "storing on a memory, study-related data associated with a protocol of the clinical study," as required by claim 1.

Brown does not disclose the aforementioned limitation and the Examiner does not rely on Brown to disclose the aforementioned limitation. Accordingly, even assuming *arguendo* that Brown could be combined with Brimm (which Applicants do not admit), the combination of references fails to render claim 1 obvious.

[41] See Brimm column 9, lines 1-6.

Brimm fails to teach or fairly suggest "storing, on the memory, patient-related data associated with the patient and the clinical study," as required by claim 1.

The Examiner alleges that "storing patient-related data associated with the patient and the medical regimen (Abstract patient information system)," discloses the aforementioned limitation. Applicants respectfully disagree.

The Examiner appears to be relying on the Abstract of Brimm. The Abstract of Brimm states:

> A hospital information system comprises a data processing system including a plurality of terminals having display means and data entry means. Patient information is entered into the system via the terminals, is organized hierarchically in the system, and may be displayed to users having proper access to the system. The system provides a time-oriented task list, which is automatically generated from data which has been entered from physicians' and nursing orders. Tasks may be charted by a system user directly onto a system form, and the task list and any associated form(s) are automatically updated.

As discussed above, and as supported by the Abstract of Brimm, the medical information system is used to replace a manual, paper based, record keeping system (e.g., medical charts).

As described above, Brimm does not disclose a clinical study. Consequently, Brimm has no reason to store "**patient-related data associated with the patient and the clinical study**," as required by claim 1. By contrast, Brimm records medications (or other care events) given to the patient as ordered by the physician.[42]

[42] See Brimm column 9, line 64 to column 10, line 15.

Brown fails to teach or fairly suggest "storing, on the memory, patient-related data associated with the patient and the clinical study," as required by claim 1.

Brown does not disclose the aforementioned limitation and the Examiner does not rely on Brown to disclose the aforementioned limitation. Accordingly, even assuming *arguendo* that Brown could be combined with Brimm (which Applicants do not admit), the combination of references fails to render claim 1 obvious.

A.2. Rejection of dependent claim 6

Brimm fails to teach or fairly suggest "at least one of the study-related data and the patient-related data are assigned to various classes, and the non-study doctor reads only information of one class out from the memory," as required by claim 6.

The Examiner relies upon column 9, line 19 of Brimm to disclose the aforementioned limitation. Column 9, lines 13-22 of Brimm states:

> After obtaining the appropriate entry into the system using predefined security measures the physician selects, from a list (not illustrated) the type of order he wants to enter (e.g. a medication).
>
> The physician then selects from list 265 which medication (e.g. Valium) is to be prescribed by placing cursor 200 over the

> designation "Valium Tablet" and selecting with the pointing device. This immediately causes the words "Valium Tablet" to appear in the "Drug Name" screen area 269.

Clearly Brimm discloses the selection of a medicine from a list of medicines. Brim does not assign medicines to different classes of medicines. Therefore, Brimm does not disclose the selection of medications from different classes of medications.

As described above, Brimm does not disclose a clinical study. Consequently, Brimm has no reason describe a non-study doctor and no reason to limit a non-study doctor to certain classes of study information. Therefore, Brimm does not teach or fairly suggest "at least one of the study-related data and the patient-related data are assigned to various classes, and the non-study doctor reads only information of one class out from the memory," as required by claim 6.

Brown fails to teach or fairly suggest "at least one of the study-related data and the patient-related data are assigned to various classes, and the non-study doctor reads only information of one class out from the memory," as required by claim 6.

Brown does not disclose the aforementioned limitation and the Examiner does not rely on Brown to disclose the aforementioned limitation. Accordingly, even assuming *arguendo* that Brown could be combined with Brimm (which Applicants do not admit), the combination of references fails to render claim 6 obvious.

Therefore, in addition to being patentable by virtue of its dependency from claim 1, claim 6 is patentable because the combination of Brimm and Brown do not teach or fairly suggest the limitations of claim 6.

A.3. Rejection of independent claim 7

Brimm fails to teach or fairly suggest an "information system for a clinical study on a patient," as required by claim 7.

For at least the reasons discussed above with regard to claim 1, Brimm does not disclose a clinical study. Therefore, Brimm does not teach or fairly suggest "[a]n information system **for a clinical study** on a patient," as required by claim 7.

Brown fails to teach or fairly suggest an "information system for a clinical study on a patient," as required by claim 7.

Brown does not disclose the aforementioned limitation and the Examiner does not rely on Brown to disclose the aforementioned limitation. Accordingly, even assuming *arguendo* that Brown could be combined with Brimm (which Applicants do not admit), the combination of references fails to render claim 7 obvious.

Brimm fails to teach or fairly suggest "a memory to store at least one of study-related and patient-related data, the memory being a computer-readable medium assigned to the patient," as required by claim 7.

For at least the reasons discussed above with regard to claim 1, Brimm does not disclose a clinical study. As a result, Brimm does not store study-related data. Further, Brimm discloses medical information system where the system (e.g., memory) is associated with a hospital. Therefore, Brimm does not teach or fairly suggest "a memory to store at least one of **study-related** and patient-related data, the memory being a computer-readable medium **assigned to the patient**," as required by claim 7.

Brown fails to teach or fairly suggest "a memory to store at least one of study-related and patient-related data, the memory being a computer-readable medium assigned to the patient," as required by claim 7.

Brown does not disclose the aforementioned limitation and the Examiner does not rely on Brown to disclose the aforementioned limitation. Accordingly, even assuming *arguendo* that Brown could be combined with Brimm (which Applicants do not admit), the combination of references fails to render claim 7 obvious.

A.4. Rejection of dependent claim 14

Brimm fails to teach or fairly suggest "at least one of the study-related data and the patient-related data are assigned to various classes, and the non-study doctor reads only information of one class out from the memory," as required by claim 14.

Brown fails to teach or fairly suggest "at least one of the study-related data and the patient-related data are assigned to various classes, and the non-study doctor reads only information of one class out from the memory," as required by claim 14.

Brown does not disclose the aforementioned limitation and the Examiner does not rely on Brown to disclose the aforementioned limitation. Accordingly, even assuming *arguendo* that Brown could be combined with Brimm (which Applicants do not admit), the combination of references fails to render claim 14 obvious.

Therefore, in addition to being patentable by virtue of its dependency from claim 7, claim 14 is patentable because the combination of Brimm and Brown do not teach or fairly suggest the limitations of claim 14.

A.5. Rejection of independent claim 17

Brimm fails to teach or fairly suggest an "information system for a clinical study on a patient," as required by claim 17.

For at least the reasons discussed above with regard to claim 1, Brimm does not disclose a clinical study. Therefore, Brimm does not teach or fairly suggest "[a]n information system **for a clinical study** on a patient," as required by claim 17.

Brown fails to teach or fairly suggest an "information system for a clinical study on a patient," as required by claim 17.

Brown does not disclose the aforementioned limitation and the Examiner does not rely on Brown to disclose the aforementioned limitation. Accordingly, even assuming *arguendo* that Brown could be combined with Brimm (which Applicants do not admit), the combination of references fails to render claim 17 obvious.

Brimm fails to teach or fairly suggest a "memory means for storing at least one of study-related and patient-related data the memory means being assigned to the patient, the memory being a computer-readable medium assigned to the patient," as required by claim 17.

For at least the reasons discussed above with regard to claim 1, Brimm does not disclose a clinical study. As a result, Brimm does not store study-related data. Further, Brimm discloses medical information system where the system (e.g., memory) is associated with a hospital. Therefore, Brimm does not teach or fairly suggest "memory means for storing at least one of **study-related** and patient-related data the memory means being assigned to the patient, **the memory being a computer-readable medium assigned to the patient**," as required by claim 17.

Brown fails to teach or fairly suggest a "memory means for storing at least one of study-related and patient-related data the memory means being assigned to the patient, the memory being a computer-readable medium assigned to the patient," as required by claim 17.

Brown does not disclose the aforementioned limitation and the Examiner does not rely on Brown to disclose the aforementioned limitation. Accordingly, even assuming *arguendo* that Brown could be combined with Brimm (which Applicants do not admit), the combination of references fails to render claim 17 obvious.

A.6. Argument Conclusion

For at least the reasons described above, Brimm and Brown, alone and in combination (assuming *arguendo* that Brown could be combined with Brimm, which the Applicants do not admit) do not teach each and every limitation of claims 1, 7 and 17. Because Brimm and Brown do not teach or fairly suggest each and every limitation of independent claim 1, Brimm in view of Brown does not render claim 1 obvious. Claims 7 and 17 are patentable for reasons at least somewhat similar to those discussed above with regard to claim 1, noting that claims 7 and 17 should be interpreted solely based on the limitations set forth therein. Claims 2-6, 8-16 and 18-23 are patentable at least by virtue of their dependency from an independent base claim.

The Applicants, therefore, respectfully request reconsideration and withdrawal of the rejection to claims 1-23 under 35 U.S.C. § 103(a).

CONCLUSION:

In light of the foregoing arguments, Appellant respectfully requests the Board to reverse the Examiner's rejections.

The Commissioner is authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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41.37(c)(1)(viii). CLAIMS APPENDIX

1. (Previously Presented) A method for carrying out a clinical study involving a patient, comprising:

storing on a memory, study-related data associated with a protocol of the clinical study;

storing, on the memory, patient-related data associated with the patient and the clinical study;

reading by a computer associated with a non-study doctor assigned to the patient at least one of the study-related data and the patient-related data, wherein

the memory is a computer readable storage medium, and

the memory is one of (1) a portable memory device transported by the patient and (2) part of a data network with limited access, the limited access being authorized by the patient.

2. (Previously Presented) The method as claimed in claim 1, wherein at least one of the study-related data and the patient-related data are stored in the memory by a study doctor.

3. (Previously Presented) The method as claimed in claim 1, wherein the non-study doctor reads at least one of the study-related data and the patient-related data from the memory before an interaction with the patient.

4. (Previously Presented) The method as claimed in claim 1, wherein the study-related data and the patient-related data are stored in the memory with standardized structuring.

5. (Previously Presented) The method as claimed in claim 1, wherein clear instructions to the non-study doctor are stored as study-related data.

6. (Previously Presented) The method as claimed in claim 1, wherein at least one of the study-related data and the patient-related data are assigned to various classes, and the non-study doctor reads only information of one class out from the memory.

7. (Previously Presented) An information system for a clinical study on a patient, comprising:

a memory to store at least one of study-related and patient-related data, the memory being a computer-readable medium assigned to the patient, the memory being one of (1) a portable memory device transported by the patient and (2) part of a data network with limited access, the limited access being authorized by the patient;

a data input device to input data being stored in the memory; and

a data reading device to read the data out from the memory, the data reading device being accessible by a non-study doctor assigned to the patient.

8. (Previously Presented) The information system as claimed in claim 7, wherein the memory is portable.

9. (Previously Presented) The information system as claimed in claim 7, wherein the memory is part of the data network, to which data input and output devices are connectable and wherein the patient authorization is required for access to the data.

10. (Previously Presented) The information system as claimed in claim 7, wherein the data reading device is portable.

11. (Previously Presented) The method as claimed in claim 2, wherein the non-study doctor reads at least one of the study-related data and the patient-related data from the memory before an interaction with the patient.

12. (Previously Presented) The method as claimed in claim 2, wherein at least one of the study-related data and the patient-related data are stored in the memory with standardized structuring.

13. (Previously Presented) The method as claimed in claim 2, wherein clear instructions to the non-study doctor are stored as study-related data.

14. (Previously Presented) The method as claimed in claim 2, wherein at least one of the study-related data and the patient-related data are assigned to various classes, and the non-study doctor reads only information of one class out from the memory.

15. (Previously Presented) The information system as claimed in claim 8, wherein the data reading device is portable.

16. (Previously Presented) The information system as claimed in claim 9, wherein the data reading device is portable.

17. (Previously Presented) An information system for a clinical study on a patient, comprising:

memory means for storing at least one of study-related and patient-related data the memory means being assigned to the patient, the memory being a computer-readable medium assigned to the patient, the memory means being one of (1) a portable memory device transported by the patient and (2) part of a data network with limited access, the limited access being authorized by the patient;

input means for storing data in the memory means; and

reading means for reading the data from the memory means, the reading means being accessible by a non-study doctor assigned to the patient.

18. (Previously Presented) The information system as claimed in claim 17, wherein the memory means is portable.

19. (Previously Presented) The information system as claimed in claim 17, wherein the memory means is part of the data network, to which data input and output devices are connectable and wherein the patient authorization is required for access to the data.

20. (Previously Presented) The information system as claimed in claim 17, wherein the reading means is portable.

21. (Previously Presented) The method as claimed in claim 1, wherein the non-study doctor is a doctor who is at least one of not associated to the clinical study and external to the clinical study.

22. (Previously Presented) The method as claimed in claim 1, wherein the clinical study is conducted to test at least one of medicaments, methods of surgical intervention, therapies, and diagnostic devices.

23. (Previously Presented) The method as claimed in claim 1, wherein the method further includes,

displaying, by the computer, at least one of the study-related and the patient-related data to the non-study doctor.

41.37(c)(1)(ix). EVIDENCE APPENDIX

As no evidence was submitted and relied upon in this Appeal, this Appendix contains no evidence pursuant to 37 C.F.R. §41.37(c)(1)(ix).

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41.37(c)(1)(x). **RELATED PROCEEDINGS APPENDIX:**

As there are no Related Proceedings associated with this Appeal, no additional information is being supplied in an Appendix pursuant to 41.37(c)(1)(x).

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